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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 327

[Docket No. FSIS-2014-0040]

RIN: 0583-AD57

Eligibility of Lithuania to Export Meat and Meat Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: USDA's Food Safety and Inspection Service (FSIS) is proposing to add the Republic of Lithuania (Lithuania) to the list of countries eligible to export meat and meat products to the United States. FSIS's review of Lithuania's laws, regulations, and inspection implementation show that its meat inspection system requirements are equivalent to the Federal Meat Inspection Act (FMIA) and its implementing regulations.

Under this proposal, meat from cattle, sheep, swine, and goats slaughtered in Lithuania, or parts or other products thereof, processed in certified Lithuanian establishments, would be eligible for export to the United States. All such products would be subject to reinspection at United States ports-of-entry by FSIS inspectors.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this rule. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the online instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2014-0040. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn,
Assistant Administrator, Office of Policy and Program
Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is proposing to amend the Federal meat inspection regulations to add Lithuania to the list of countries eligible to export meat and meat products to the United States (9 CFR 327.2(b)). Lithuania is not currently listed as eligible to export such products to the United States.

Statutory Basis for Proposed Action

Under the FMIA and the regulations that implement it, meat and meat products imported into the United States must be produced under standards for safety, wholesomeness, and labeling accuracy that are equivalent to those of the United States (21 U.S.C. 620). The FMIA also requires that the livestock from which such imports are produced be slaughtered and handled in connection with slaughter in a manner that is consistent with the Humane Methods of Slaughter Act (7 U.S.C. 1901-1906). Section 327.2 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export meat and meat products to the United States.

Paragraph 327.2(a) of 9 CFR requires that a foreign country's meat inspection system provide standards equivalent to those of the United States and to provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's legal authority and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem inspection, humane methods of slaughter and handling, and post-mortem inspection by, or under the direct supervision of, a veterinarian; (2) official controls by the national government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering and preparation of product by inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of product at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the FMIA and its implementing regulations (9 CFR 327.2(a)(2)(ii)).

The country's inspection system must also impose requirements equivalent to those of the United States with respect to: (1) organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) national government control and supervision over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification and residue standards; and (7) any other inspection requirements (9 CFR 327.2(a)(2)(i)).

A foreign country's inspection system must be evaluated by FSIS before eligibility to export meat and meat products to the United States can be granted. This evaluation consists of two processes: a document review and an on-site review. The document review is an evaluation of the laws, regulations, and other written materials used by the country to effect its inspection program. FSIS requests that countries provide information about their inspection systems through its self-reporting tool (SRT).¹ Through the SRT, FSIS collects information on practices and procedures in six areas, known as

¹ The SRT is a standardized questionnaire that FSIS provides to foreign governments to gather information that characterizes foreign inspection systems according to the six equivalence components and as required by 9 CFR 327.2(a)(2)(iii). FSIS asks foreign governments to submit documentation, such as their inspection system laws, regulations, and policy issuances, that supports their responses to the SRT questions.

equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Chemical Residue Testing Programs, and (6) Microbiological Testing Programs. FSIS evaluates the information submitted to verify that the critical points in the six equivalence components are addressed satisfactorily with respect to standards, activities, resources, and enforcement. If the document review is satisfactory, an onsite review is scheduled using a multidisciplinary team to evaluate all aspects of the country's inspection program. This comprehensive process is described more fully on the FSIS Web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence/equivalence-process-overview>.

The FMIA and implementing regulations require that foreign countries be listed in the CFR as eligible to import meat and meat products into the United States. FSIS must engage in rulemaking to list a country as eligible. Countries found eligible to import meat or meat products into the United States are listed in the meat inspection regulations at 9 CFR 327.2(b). Once listed, the government of an eligible country must certify to FSIS that establishments that wish to export meat products to the United States are operating under requirements equivalent to

those of the United States (9 CFR 327.2(a)(3)). Countries must renew certifications of establishments annually.

Section 20 of the FMIA (21 U.S.C. 620) prohibits importing into the United States adulterated or misbranded carcasses, parts of carcasses, meat, or meat products of amenable species, which are capable of use as human food. To verify that products imported into the United States are not adulterated or misbranded, FSIS reinspects and randomly samples those products at import, before they enter U.S. commerce.

Evaluation of the Lithuanian Meat Inspection System

In 2004, the government of Lithuania initially requested approval to export meat, poultry, and egg products to the United States. After several consultations and FSIS visits to Lithuania, the country amended its request to include only meat and meat products in January 2012. If approved, Lithuania stated its immediate intent to export canned, dried, or smoked meat products of beef and pork to the United States. However, if approved, Lithuania would not be precluded from exporting other meat products in the future provided the products meet all applicable requirements for those products established by the USDA's Animal and Plant Health Inspection Service (APHIS) as well as by FSIS.

FSIS conducted a document review of Lithuania's meat (slaughter and processing) inspection system through information

provided through the SRT to determine whether that system is equivalent to the United States' meat inspection system. Based on that review, FSIS concluded that Lithuania's laws, regulations, control programs, and procedures were sufficient to achieve the level of public health protection required by FSIS.

Accordingly, FSIS proceeded with an initial on-site audit of Lithuania's meat inspection system from September 10 to 26, 2012, to verify whether Lithuania's State Food and Veterinary Service (SFVS), which is Lithuania's central competent authority in charge of food inspection, effectively implemented a meat inspection system equivalent to that of the United States. FSIS concluded that Lithuania's meat inspection system met each equivalence component except sanitation. FSIS found that Lithuania had modified its inspection requirements since the document review, and no longer required written standard operating procedures for sanitation (Sanitation SOPs) from establishments. Additionally, the sanitation programs at all of the establishments visited by the audit team lacked measures to prevent recurring deficiencies that could result in direct product contamination or adulteration.

The initial on-site audit revealed other issues of concern, but none that resulted in a failure to meet the other five equivalence components. SFVS took immediate corrective actions to address the audit team's findings and provided a corrective

action plan, which included new regulations, procedures, implementation measures, and verification activities. FSIS reviewed the plan and concluded that it addressed all of the audit findings. The initial audit report contains a full discussion of the corrective actions proffered by SFVS:

<http://www.fsis.usda.gov/wps/wcm/connect/600646a6-75fb-4d24-b82e-02361c06f3db/Lithuania-2012.pdf?MOD=AJPERES>.

FSIS conducted a second on-site audit from September 16 to 24, 2013, to verify that Lithuania had satisfactorily implemented all the laws, regulations, and instructions to the field that FSIS found to be equivalent during the document analysis and to verify that all outstanding issues identified during the previous audit had been resolved. FSIS concluded, based on this audit, that Lithuania had satisfactorily addressed all audit findings and had met the FSIS equivalence criteria for all six components. For example, during the audit, FSIS verified that Lithuania had reestablished a regulatory requirement that establishments develop and maintain written Sanitation SOPs as a condition for gaining certification to export meat products to the U.S. FSIS also verified that Lithuania's inspection system has established official procedures to verify that each establishment has an effective sanitation program that meets the regulatory requirements, including development and maintenance of Sanitation SOPs.

Similarly, FSIS previously found that the SFVS did not ensure that establishments' HACCP corrective actions included preventive measures, or that establishments were documenting their monitoring or verification activities. During the most recent audit, FSIS verified that inspection program personnel are now effectively performing verification activities designed to ensure that establishments are properly documenting their monitoring and verification activities and are documenting preventive measures in response to HACCP system deviations.

In summary, FSIS has completed the document review, on-site audit, and verification of corrective actions as part of the equivalence process, and all outstanding issues have been resolved. FSIS has determined that, as implemented, Lithuania's meat inspection system (slaughter and processing) is equivalent to the United States' meat inspection system. The full report on Lithuania's meat inspection system (slaughter and processing) can be found on the FSIS Web site at:

http://www.fsis.usda.gov/wps/wcm/connect/87776212-0dec-44c3-8ee4-155ad0a02b15/Lithuania_2013_FAR.pdf?MOD=AJPERES.

Should this rule become final, the Government of Lithuania must certify to FSIS that those establishments that wish to export meat or meat products to the United States are operating in accordance with requirements equivalent to those of the United States. FSIS will verify that the establishments

certified by Lithuania's government are meeting the United States' requirements through periodic, regularly scheduled audits of Lithuania's meat inspection system. Certified establishments may export to the United States any meat or meat products from cattle, sheep, swine, and goats (9 CFR 327.2(b)).

Although a foreign country may be listed in FSIS's regulations as eligible to export meat and meat products to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. These requirements include restrictions under 9 CFR part 94 of APHIS' regulations, which also regulate the export of meat products from foreign countries to the United States.

If this proposed rule is adopted, all meat and meat products exported to the United States from Lithuania will be subject to reinspection at U.S. ports-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count.

In addition, FSIS will conduct other types of reinspection activities, such as incubation of canned products to ensure product safety and taking product samples for laboratory analysis for the detection of drug and chemical residues, pathogens, species, and product composition. Products that pass reinspection will be stamped with the official USDA mark of

inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry, and within 45 days they must be returned to the country of origin, destroyed, or converted to animal food (subject to approval by the Food and Drug Administration), depending on the violation. The import reinspection activities can be found on the FSIS Web site at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures/fsis-import-reinspection/CT_Index9.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a "non-significant" regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

Expected Cost of the Proposed Rule

If this rule is finalized, Lithuania intends to start with exporting canned, dried, or smoked beef and pork products to the United States. As noted above, if this rule is finalized, Lithuania would not be precluded from exporting other meat products in the future if the products meet all applicable APHIS and FSIS requirements for those products. Lithuania, however, will not be limited to the export of canned, dried, or smoked beef and pork products only. Given the limited market in the United States for Lithuanian meat products and Lithuania's low projected export volume, there is likely to be little, if any, impact on the United States economy.

Lithuania is a small beef producer with limited beef export capacity. Its maximum beef export to the world was achieved in 2011, when it exported \$130 million, or 25,000 metric tons (MT), worth of beef,² mainly to the European Union and Russia.

Based on analysis of Lithuania's exports to Russia,³ FSIS estimates that Lithuania has an excess beef export capacity of \$26 million (\$130 million - \$104 million = \$26 million) in value, or 3,000 MT (25,000 MT - 22,000 MT = 3,000 MT) in volume, that could be exported to the United States.

² This data is from Eurostat, the statistical office of the European Union, and is based on Lithuania's official statistics. It is also available at the Global Trade Atlas database at: <http://www.gtis.com/gta/secure/gateway.cfm>.

³ Ibid.

Accordingly, allowing Lithuanian beef exports to enter the 13,050,000 MT⁴ United States beef market is expected to have minimal effect (3,000 MT represents a 0.023% increase), leaving the total United States beef supply almost unchanged. Because importing beef from Lithuania is not expected to greatly alter the United States beef supply, it will not contribute to any price change in that market.

Lithuanian data from CY 2013⁵ shows that this country has reached its maximum pork export capacity, meaning it will export little, if any, pork to the United States. Considering that the United States pork supply is 11,212,000 MT (CY 2013),⁶ it is unlikely that imports from Lithuania will result in price changes in the United States pork market.

The above cost analysis is based on Lithuania's full export capacity. Currently, however, only six Lithuanian establishments intend to export product to the United States. Four are meat processors only, one is a slaughter facility, and one conducts both meat slaughter and processing. Of the four processing facilities, three process beef and pork, and one processes pork only. The slaughter-only facility and the

⁴ Source: Foreign Agricultural Service (FAS) Production, Supply and Distribution (PSD) data, available at: <https://apps.fas.usda.gov/psdonline/psdQuery.aspx>.

⁵ This data is from Eurostat, based on Lithuania's official statistics. It is also available at the Global Trade Atlas database at: <http://www.gtis.com/gta/secure/gateway.cfm>.

⁶ Source: FAS PSD data, available at: <https://apps.fas.usda.gov/psdonline/psdQuery.aspx>.

facility that conducts both slaughter and processing both handle beef and pork. The combined export capacity of these six establishments is much less than Lithuania's total export capacity. With no price change expected in U.S. meat markets, adopting this proposed rule would lead to no negative effects on U.S. consumers.

Lithuanian companies that export product to the U.S. or U.S. companies that import products from Lithuania to the United States will incur standard costs such as export fees and freight and insurance costs. They will be willing to bear these costs, however, because of the anticipated financial benefits associated with marketing their products in the United States

Expected Benefits of the Proposed Rule

Adoption of this proposed rule will increase trade between the United States and Lithuania. The volume of trade stimulated by the proposed rule is likely to be small and is expected to have little or no effect on U.S. meat supplies or meat prices. U.S. consumers, however, are expected to enjoy more choices when purchasing meat and meat products. Lithuanian establishments seek to export commercially sterile meat products, including canned meat products and ready-to-eat products like salamis and other dried and smoked meats to the United States. The proposed rule would, therefore, expand choices for U.S. consumers and promote economic competition.

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

Paperwork Reduction Act

No new paperwork requirements are associated with this proposed rule. Foreign countries wanting to export meat and meat products to the United States are required to provide information to FSIS certifying that their inspection systems provide standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. FSIS provided Lithuania with questionnaires asking for detailed information about the country's inspection practices and procedures to assist that country in organizing its materials. This information collection was approved under OMB number 0583-0153. The proposed rule contains no other paperwork requirements.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information

technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this proposed rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted, (2) no retroactive effect will be given to this rule, and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

USDA Non-discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in,

deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

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http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail

U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410

Fax

(202) 690-7442

E-mail

program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at:

<http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 327

Imported products.

For the reasons set out in the preamble, FSIS is proposing to amend 9 CFR part 327 as follows:

PART 327--IMPORTED PRODUCTS

1. The authority citation for part 327 continues to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 327.2 [Amended]

2. Section 327.2 is amended in paragraph (b) by adding "Lithuania" in alphabetical order to the list of countries.

Done at Washington, DC, on: December 12, 2014.

Alfred V. Almanza

Acting Administrator.

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